



St. Paul's Hospital Millennium Medical College (SPHMMC)

Department of Pathology

**Quality Management in the Histopathology Lab: A Single
Institutional Experience from May 2018- August 2022, SPHMMC,
Addis Ababa, Ethiopia.**

Investigator: Daniel Kassie, MD

Addis Ababa, Ethiopia

November, 2022



St. Paul Hospital Millennium Medical College

Quality Management in the Histopathology Lab: A Single Institutional Experience from May 2018 - August 2022, SPHMMC, Addis Ababa, Ethiopia.

Investigator: Dr. Daniel Kassie (MD)

Advisor: Dr. Bereket Berhane (MD, Assistant Professor of Anatomic Pathology)

**A Research Report submitted to the Department of Pathology at St. Paul's
Hospital Millennium Medical College: In partial fulfilment for the
Requirement of specialty certificate in of Anatomic pathology**

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Abstract

Background: To be of utility, the pathology report must be accurate, complete and timely. And, these three qualities, in turn, are crucially dependent on many variables in the specimen test-cycle, starting from the pre-analytic to analytic to post-analytic. The last few years, especially since the first National Cancer Control Plan of Ethiopia that was published in 2015 by the Federal Ministry of Health came to be implemented on the ground, a remarkable expansion of pathology laboratories was seen across the nation. But except for one paper that tried to audit the overall capacities (as regards equipment resource) of pathology labs, no facility-based research has been carried out so far to assess the performance of pathology labs by using acceptable metrics across the whole range of the specimen test cycle.

This study aims to identify different factors affecting the timeliness and completeness of pathology reports, two factors which are considered as major quality indicators. This will help identify the gaps and improve the quality of service provided by the laboratory in the future.

Objective: The main objective of this study is to assess selected pre-analytical factors, analytic factors and post analytic factors affecting quality of pathology service.

Methods: A retrospective chart review method was used. Sampling was done using stratified random sampling. Sample size was calculated after stratifying the cases in to each respective year starting from May 2018 to Aug 2022. A review of 1783 pathology requisition forms and final report were done. Pre-analytic factors (ID, name, age, sex, clinical information, clinical diagnosis, clinician information), analytic factors (presence of gross, microscopy and diagnosis) and post analytic factor (Turnaround time of a pathology report) were audited. Data was entered into SPSS 26 and descriptive analysis done.

Result: A total of number 1783 biopsy reports were evaluated. In the study period 2018 to 2022, histopathology request forms lacked patient age in 1.5%, sex in 1.1%, medical record number in 7.2%, and patient contact information in 4 % in the patient identification information section of the requisition form, while patient full name was available in all of the cases. Clinician contact information was missing in most of the cases (85.3%) while clinician name was provided in higher percentage on request forms (82.2%).

Clinical history and clinical diagnosis were missing in 1 out of 4 request forms. Most of the requisition forms with incomplete data were submitted by St Paul's Hospital Millennium Medical College (72.4%), while majority of wet surgical biopsy specimens originated from the department of Gynecology and Obstetrics, accounting for 52.4%. Specimen information was mentioned in most of the requisition forms – site in 98.5%, type of procedure in 86%, and date of procedure in 97%. All the requisition forms reviewed had gross, microscopy and diagnosis.

The mean turnaround time (TAT) was 16.29 days (10th–90th percentile range, 10–26 days). The mean TAT showed gradual improvement from the year 2019 to 2022 from 18.73 (10th–90th percentile range, 10.5–27 days) to 14.5 (10th–90th percentile range, 7–25 days).

Conclusion and Recommendation: The research finding show gaps in pre-analytic factors (including patient identification variables, specimen identification, etc...) that need to be improved upon, especially when considering their impact on the overall quality of the pathology report.

Despite the progress and improvement seen over the past five years, the TAT for biopsy is still lagging in achieving the target set by the quality team of the department.

Finally, the drafted User's Manual must be published and distributed. Besides, the rejection criteria (see annex) developed by the quality team should also be instituted and communication between the lab and the different health facilities that send samples to the lab, especially with the different departments within SPHMMC, must be improved if the targets set by quality team are to be realized.

1. Introduction

1.1. Background

The International Standardization Society (ISO) defines quality as “the totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs”

(1). According to the World Health Organization (WHO), it is defined as “the total set of characteristics of an entity that affect its ability to satisfy stated and implied needs and to ensure the consistent and reliable performance of services or products in conformity with specified requirements.” (2)

Laboratory quality can be defined as accuracy, reliability and timeliness of reported test results. In other words, to be useful in a clinical or public health setting, the test result must be as accurate as possible, all aspects of the laboratory operations must be reliable, and reports must be timely.(2)

Ensuring quality of a laboratory service is dependent on a well-developed quality management system (QMS), which can be defined as “coordinated activities to direct and control an organization with regard to quality”. In a quality management system, all aspects of the laboratory operation, including the organizational structure, processes and procedures need to be addressed to assure quality.

There are many procedures and processes that are performed in the laboratory, and each of these must be carried out correctly in order to assure accuracy and reliability of testing. An error in any part of the cycle can produce a poor laboratory result, and a method of detecting these errors at each phase of testing is needed if quality is to be assured. According to ISO standard, laboratory processes are divided into pre-examination, examination and post-examination categories.

Comparable terms in current laboratory use include: pre-analytic, analytic and post-analytic processes; or pre-test, test and post-test processes.

Quality control (QC) is a major component of QMS and it is used to monitor, to detect, to evaluate and to correct errors. (2)

Quality in the practice of surgical pathology may be defined as the production of accurate, timely, and complete reports. This requires substantial investment in the basic physical infrastructure, equipment, reagents and most importantly in the health personnel who will be tasked with the day-to-day activity of the overall process. Quality assurance and improvement

works best when it is woven into the systems of surgical pathology with well-informed, well-trained, and knowledgeable staff .(3)

QMS has been gradually instituted at SPHMMC's department of pathology starting around 8 years back, when the pathology lab started providing services. The quality management team was established four years back. The team is supervised by the department head and is tasked to a 6-person quality team lead by a senior pathologist. Other members of the team are the lab supervisor (a senior histotechnologist with BSc in lab, certificate in histotechnology, MSc in lab management and further training in leadership), two general practitioners, one histotechnician, and a senior resident in anatomic pathology.

The quality control team holds weekly meeting (on Fridays) and a monthly report of their activity is presented to all members of the department and residents on the first Monday of every month. The report, prepared and presented by the quality control officers and histotechnologist, covers all monthly pre analytic, analytic and post analytic quality metrics important for the specimen test cycle - in surgical pathology, non-gynecologic cytopathology and hematopathology services.

The meeting strives to identify problems and defects in that particular month, and potential solutions will be discussed with every stakeholder. Specific interventions will be planned and results will be assessed in the coming month.

Other instituted QC measures routinely performed at the department include running QC before and after stains (routine Hematoxylin and Eosin stains) – i.e., before staining all biopsy specimens scheduled to be stained for that day; evaluating for slide qualities during biopsy signing out sessions using a format adopted from the ASCP (American Society of Clinical Pathologist) guideline (see annex); holding weekly slide sessions for difficult cases; and, off-site consultation for difficult cases that need further subspecialist pathologists expertise for interpretation.

And, finally, as part of the overall performance improvement program (PIP) under the QMS adopted by the department, a User's Manual was developed by the quality team and the manual is in the process of getting distributed to all stake holders within and outside SPHMMC – i.e., all health institutions that send sample to the pathology lab. The manual details the different specimen test cycles within the anatomic pathology lab, and lists the minimum information that

needs to be included in a surgical biopsy requisition form, rejection criteria for wet surgical specimen and cytopathology specimens, specimen discarding and archiving protocol and other relevant information needed for a seamless QMS in the pathology lab.

Some of the frequently encountered problems that are noted during the monthly QC meetings pertain to incompleteness of the pathology requisition forms - including incompleteness in demographic variables, inadequate or absent clinical information and radiologic information; inconsistency in maintaining quality of slides; and long turnaround times (TATs.)

2.1. Statement of the problem

To be of utility, the pathology report must be accurate, complete and timely. And, these three qualities, in turn, are crucially dependent on many variables in the specimen test-cycle, starting from the pre-analytic to analytic to post-analytic.

By its very nature, the quality of surgical pathology depends heavily on the inputs of surgeons and clinicians and other health actors that are not involved in its processing. In particular, the behavior and actions of these various health professionals and their influence on the quality of the pre-analytic variables has been well documented in numerous published researches.⁵ Other factors that impact the quality of the pathology laboratory workflow include handling of biopsy immediately in the operating theater (devitalization time), type and amount of fixative used, type of container used for transportation, information supplied on requisition forms, proper handling and grossing of the specimen, specimen processing, quality and supply of chemicals and reagents, preventive maintenance and calibration of lab equipment, training, skills and competence of histotechnicians and pathologists, etc. ... are some of the factors that directly or indirectly impact the quality of the final pathology report.

The pathology laboratory at SPHMMC, which started service around 2014, is one of the biggest such laboratories in the whole nation. Currently it processes around one thousand wet surgical biopsy specimens originating from different departments of SPHMMC and more than 10 extra-institutional health facilities. The pathology report generated daily by the pathology department has significant implication for patient management, and as such all three aspects of quality (timeliness, completeness and accuracy) must be maintained.

Some of the major and recurrent problems identified by the QC team of SPHMMC's pathology lab are incomplete and/or absent patient identification variables, clinical information, specimen information, and managing clinician's details.

1.3. Rationale for the study

The last few years, especially ever since the first National Cancer Control Plan of Ethiopia that was published in 2015 by the Federal Ministry of Health came to be implemented on the ground, a remarkable expansion of pathology laboratories was seen across the nation, But except for one paper that tried to audit the overall capacity (especially as regards equipment resource) of pathology labs, no facility-based research has been carried out so far to assess the performance of pathology labs by using acceptable metrics across the whole range of the specimen test cycle.

This study is the first to audit selected pre analytic, analytic and post-analytic QC factors, including availability of patient identification, clinical and specimen information in pathology request forms; presence of the gross examination, microscopic description and diagnosis; and the TAT.

In order to do this, surgical biopsy reports and requisition forms at the archive of SPHMMC department of pathology will be reviewed, and it is hoped the audit will help identify gaps in the current QMS, provide insight into ways of improvement the current practice, and act as a foundational reference material for other institutions and future researches in the specific area.

2. Literature review

2.1 Pre analytic phase

Pre-analytic phase of histopathology service starts with decision to collect specimen for pathology examination made by clinical service provider with specialized knowledge of the disease and appropriate sampling method. After collection, the specimen should be submitted with appropriate fixative, specimen identification, properly filled requisition form containing all relevant information (including patient name, detail of requesting medical personnel, date and time of collection, sampling site, clinical history and pertinent information and test required) and then properly transported to the pathology laboratory. Any defect in this initial phase of the specimen-test cycle will limit the pathologist's ultimate job of producing a reliable, accurate and timely report. Many researches have demonstrated that most errors in the pathology lab occur from mistakes in the pre-analytic phase of testing^{4, 5, 10}(4,10)

A Q probe (an external peer comparison program sponsored by the College of American Pathologists that addresses process, outcome, and structure-oriented quality assurance issues) of 771475 surgical pathology cases done in 1999 by The College of American Pathologists (CAP), involving 341 hospitals from the USA, Canada, the United Kingdom, Australia, New Zealand, Hong Kong and Belgium, showed 5594 (0.73%) of the cases 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 90th percentile, 0.08%. The highest rate of cases with inadequate clinical information was 20%.

In addition, this study also showed absence of adequate clinical information resulted in 32% of cases were judged to have been delayed; 15.1% of cases experienced a delay of more than 1 day. The vast majority (68%) had no delay, and 16.2% experienced a delay that was 1 day or less and 4.2% of the cases the diagnosis was substantially changed because of the additional clinical information. (5)

Another such study, in which 417 labs participated, showed identification and accessioning deficiencies were available in 60 042 (6%) out of a total 1 004 115 cases accessioned (median deficiency rate of 3.4%). Errors related to specimen identification accounted for 9.6% of these deficiencies. The most common deficiency was "no clinical history or diagnosis present on the requisition slip," which represented 40% of all deficiencies. (6).

Another study done at United Kingdom, Royal Hallamshire Hospital in Sheffield showed that the date of specimen collection was frequently reported (98.2%) but the time of sampling was usually absent (79.3%), adequate clinical information was absent in 6.1% of the cases and A differential diagnosis was given in 53.1% of requests. They also reported Surgical trainees were more likely than medical trainees to give an inadequate clinical history (10.1% v 1.5%; $p < 0.0001$) and less likely to proffer a diagnosis (38.3% v 75.0%; $p < 0.0001$). (7)

A study done in the Armed Forces Institute of Pathology (AFIP), Rawalpindi, in Pakistan, audited 500 cases out of an annual workload of 25000 biopsies for completeness of pathology request forms in 2007, and it showed that age was not mentioned in 29 (5.8%) cases; no clinical history or differential diagnosis was given in 170 (34%) cases; site of biopsy was absent in 65 (13%) cases; and, the name of requesting clinician or any contact information was present in only 115 (23%) of request forms. (8)

Another study done in a Nigerian teaching hospital, which audited 100 randomly selected surgical biopsy request forms from different department over the span of 3 months, showed age of patient, clinical history and site of biopsy were documented in 75%, 50% and 47%, respectively. Investigations already done (18%) and examination findings (25%) were the least documented. Provisional diagnosis was documented in 84 of 100 cards and 69% (58/84) of which were concordant with final histopathological diagnoses. In only three (3%) forms were all required information documented. They also reported absence of clinical information prolonged their TAT from 5 days to 5.6 days.(9)

In another study done in South Africa, Tygerberg Hospital, date of birth was missing in 3.7%, gender in 4.9%, clinician's name in 7.4%, and no clinical diagnosis were available for 19% of the cases. This study also showed type of specimen, date and time were not available for in 11%, 15.3% and 19.9 % of cases, respectively. (10)

2.2. Analytic phase

The analytic phase of the test cycle begins with gross examination of the specimen and ends with diagnosis.(3) Analytic phase of a pathology report includes specimen accessioning to the laboratory, gross dissection, tissue processing, embedding, staining and sectioning of surgical specimen and generating consistent complete report that contain all information required for decision making in a format that is easy to interpret.(4)

In the absence of a better method, judging the correctness of surgical pathology diagnoses has become an exercise in peer review and may be the most important measure of quality with respect to patient care. Second review of cases before verification has been shown to reduce the number of amended reports. Thus, as a preventative measure many institutions have installed second pathologist review before sign-out on selected cases.(3)

A study done by the College of American Pathologists as quality improvement program which included a total of 136 institution (127 of them located in USA and the rest in Lebanon, Saudi Arabia and Canada) in 2011, and in which a total of 427255 were reviewed, 1811 cases (0.4%) had some type of mislabeling. The overall mislabeling rates per 1000 were 1.1 cases, 1.0 specimen, 1.7 blocks, and 1.1 slides. Of all mislabeling events, 27.1% were cases, 19.8% specimens, 25.5% blocks, and 27.7% slides. The work locations at which the errors occurred were 20.9% before accessioning, 12.4% at accessioning, 21.7% at block labeling, 10.2% during gross pathology, and 30.4% at tissue cutting.(11)

Routinely including a statement in the gross description that the specimen is labeled with the patient's name and is properly identified was also associated with lower rates of specimen mislabeling. The errors were corrected before reports were issued 96.7% of the time; for 3.2% of errors, a corrected report was issued. In 1.3% of error occurrences, participants gauged that patient care was affected. (mislabeling of cases, specimens, blocks, and slides: a college of American pathologists study of 136 institutions). (11)

2.3 Post analytic phase

The post-analytic phase begins with dictation of the gross and microscopic examination and the final diagnosis and includes transcription, report correction, verification, and report delivery.(3) In addition, it also includes retention and disposal of tissue blocks, slides and remnant tissue and archiving of patient data and report.(4)

TAT is a clinician satisfier and is an important indicator of efficiency in the anatomic pathology laboratory. Per Collage of American Pathologists measurement of the TAT for routine surgical pathology biopsy reports that meet a minimum two business day requirement, an indicator of a laboratory's efficiency, and also impacts coordination of patient care.(12)

As compared to CAP, the royal collage of pathologist of Australasia regulation as regards TAT are as follows: 80% of specimens within 5 working days, 90% within 10 working days and 98% within 15 working days. (13).

While the Royal collage of pathology of the UK states key performance indicator (KPI) is to report 80% of diagnostic cases within 7 days and , and 90% reported within 10 calendar days. A CAP study which included 56 institutions evaluated the TAT for 2763 large and complex cases in 2011 and the TAT was 2.72 calendar days (10th–90th percentile range, 1.2–6.3 days). Compared with routine cases, special handling cases (decalcification, reprocessing of poorly fixed blocks, re-embedding of poorly oriented tissue, or additional gross examination with submission of additional tissue blocks, IHC, molecular studies and flow cytometry) had a TAT about 2 days longer (median, 4.13 versus 1.94 days), with a wide 10th to 90th percentile range (9.11–1.33 days for special handling cases and 5.99–0.98 days for routine cases).(14)

A study done in teaching hospital, Ghurki Trust Teaching Hospital Pakistan; audited TAT of 1000 samples received in the course of nine months and the minimum TAT was 2 days and the maximum TAT was 15 days. The mean TAT was calculated to be 5.6 days.(15)

While studies done in west Africa Nigeria, Histopathology Department of the Jos University Teaching Hospital the mean laboratory turnaround time was 7.5 ± 9.7 days with a range of 3–18 days. As much as 20.8% of reports were ready for dispatch by day 3 and 100% by day 18, while retrospective analysis of 1085 done on surgical biopsies at the Department of Pathology, University College Hospital (UCH), Ibadan showed a TAT for all samples was 22 days (± 10 days).(16, 17)

A study done in east Africa; Kenya showed mean intra-laboratory turnaround time of 16.2 days from the time of accession to dispatch with a range of 3-59 days. A total of 1065 (56.3%) of the reports had been dispatched by fourteen days while 1726 (91.2%) of them were dispatched by thirty days while a single study done in Ethiopia shows Out of the 11 histopathology laboratories assessed, the minimum stated TAT was 7 days and the maximum was 30 days; and on average it is 18 days to have a result for a biopsy.(18, 19) St Paul hospital millennium medical collage pathology user guideline shows its target TAT is 14 days.(20)

3. Objective

3.1. General objective

- To assess pre-analytic, analytic and post-analytic metrics in surgical biopsy reports.

3.2. Specific objective

- To audit pre-analytic metrics in surgical biopsy reports
- To audit analytic metrics (presence of proper gross microscopic description and diagnosis) in surgical biopsy reports
- To audit post-analytic metrics (TAT) in surgical biopsy reports

4. Method

4.1. Study setting

The study was conducted at Saint Paul's Hospital Millennium Medical College, one of the largest public owned hospitals and tertiary level teaching institution in the nation, which is located in Addis Ababa, in Gulele sub city, 1271 Swaziland Street.

4.2. Study design and period

A retrospective analysis of archived files was conducted on patients who had biopsy submitted to department of pathology at SPHMMC from May 2018 - June 2022. The study was carried out from 1st of September through 30th of November.

4.3. Source population

All surgical patients who had undergone a surgical procedure which have their sample submitted for pathology evaluation between the years May 2018 to August 2022 at SPHMMC were the study population.

4.4. Study population

All Selected patients who had biopsy specimens submitted for histopathologic evaluation from the year May 2018 to August 2022 to the department of pathology, SPHMMC and who fulfil the inclusion criteria were the study population.

4.5. Sampling procedure

Stratified random sampling was used by dividing the sample in to the year they were reported in, from 2018 to 2022. After stratification, simple random sampling was done by dividing the total number of surgical biopsies signed out in that specific year, N (N=1908 in 2018, N=7144 in 2019, N=4446 in 2020, N=7479 in 2021 and N=5800 in 2022) by the sample size calculated for each using single proportion formula resulting in the interval, K.

Finally, every kth medical record was included until the final patient in that particular year.

4.6. Sample size

The estimated minimum required sample size for each year was calculated using single proportion formula with 95 percent confidence interval (Z) and 5 percent error of margin (Moe). Since similar studies are lacking; population proportion (p) of 50 percent was used. Total sample size (N) was N=1943 in 2018, N=7144 in 2019, N=4446 in 2020, N=7479 in 2021, and N=5800 in 2022.

$$n^o = \frac{Z^2 \cdot p(1-p)}{(Moe)^2} = \frac{1.96^2 \times 0.5(1-0.5)}{(0.05)^2} = 380$$

Since the sample size is finite, correction formula was used.

$M_{2018} = \frac{N_0}{1 + \frac{N_0 - 1}{\text{sample size}}} = \frac{384}{1 + \frac{384 - 1}{1908}} = 320$

$$M_{2018} = \frac{n^0}{n^0 + \left(\frac{n^0 - 1}{N} \right)} = \frac{384}{1 + \frac{384 - 1}{1908}} = 320$$

The same was done for the rest four years. Calculated sample size was 320 samples from 2018, 365 samples from 2019, 354 samples from 2020, 365 samples from 2021, and 360 samples from 2022 were calculated using the formula.

4.7. Variables

- 1. Pre analytic variables:** Identification, managing physician information, clinical information and specimen information.
- 2. Analytic variables:** Gross description, microscopic description and clear diagnostic terminology.
- 3. Post analytic variables:** Turnaround time of surgical biopsy specimens

4.8. Inclusion and exclusion criteria

4.8.1. Inclusion criteria:

All surgical specimens submitted for histopathologic evaluation

4.8.2. Exclusion criteria:

All specimens with incomplete entry at accessioning (including specimens which were rejected and specimens returned to patients or family members for various reasons)

All renal core needle biopsy specimens were excluded (because they are signed out through a separate system)

All biopsies that are not signed out due until August 30 for different reasons.

4.9. Data source and data collection procedure

Data for selected surgical biopsy reports was collected from electronic records and archived requisition forms from the department of pathology. All selected pathology report records from May 2018 to August 2022 were evaluated and data were collected using questioner tool prepared for this study. Unique patient identifier pathology number will be used. Data collection was done by one trained histotechnologist and the PI using the data abstraction checklist and it will be supervised by the main researcher.

4.10 Operational definition

Turnaround time: The day the specimen is accessioned in the lab to the day the final report is signed out.

Accession Date: The date recorded in the laboratory/hospital information system that documents when a specimen was received by the laboratory.

Signed Out/Verified: When a pathology report is released with a final diagnosis.

4.11. Data Analysis Plan and Procedures

After being cleaned and coded, the data was entered into SPSS version 26. Descriptive analysis of the data was done.

4.12. Ethical Consideration

Ethical clearance was obtained from St Paul hospital millennium medical collage Institutional review board, following the approval of research advisor. Client names was not be recorded on the data collecting format to maintain confidentiality and patient information was not and will not be shared to any other organ.

4.13. Dissemination of result

The finding of the research will be shared with every department at Saint Paul millennium medical Hospital submitting biopsy specimens to department of pathology. The finding will also be shared internally to pathology department residents, seniors and histotechnologist.

5. Result

5.1. General

5.1.1 Biopsy submitting institution

Among 1783 biopsies received review of requestion forms showed 77.8 percent of the biopsies received are from St. Paul Hospital millennium medical collage while other institutions in Addis Ababa contributed for the remaining 22.2 percent of the biopsies with second and third largest being Ras Desta Hospital and Zewditu memorial Hospital.

Submitting Hospital	Frequency	Percent
Saint Paul Hospital	1387	77.8
Zewditu Memorial Hospital	92	5.2
Ras Desta Hospital	132	7.4
St peters Hospital	43	2.4
Black lion Hospital	14	0.8
Chanco HC	5	0.3
St. Luke Hospital	36	2.0
Others	46	2.6
Werabe specialized Hospital	9	0.5
yekatit 12 Hospital	8	0.4
Wolayita University Hospital	11	0.6
Total	1783	100.0

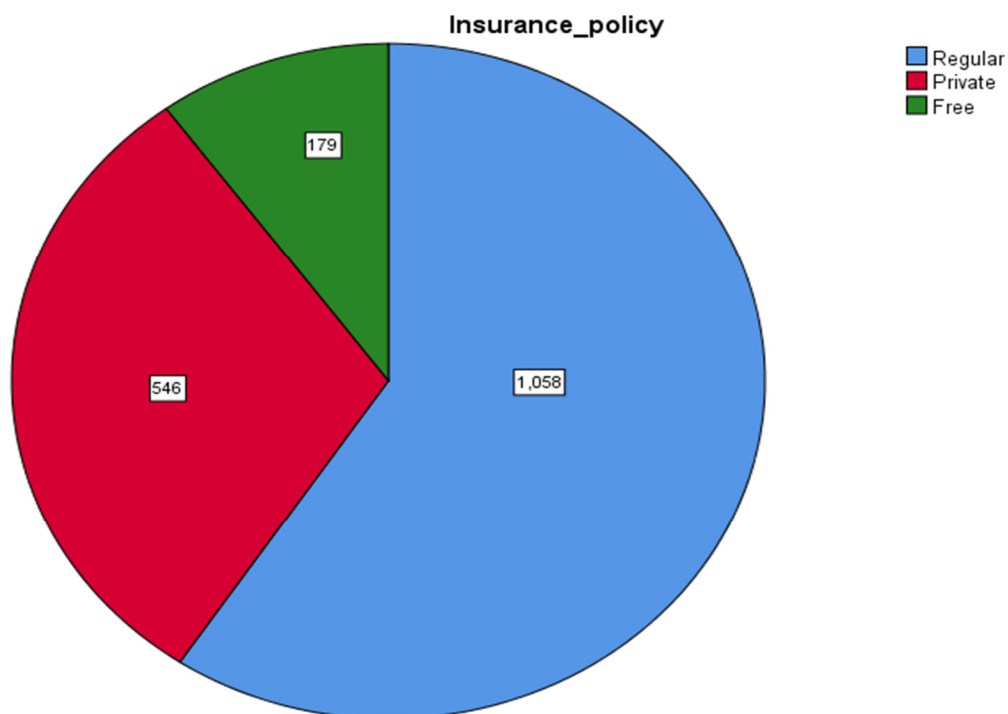
5.1.2 Submitting Department

Majority of the biopsies are submitted by gynecology and surgical departments with 38.8 and 38.6 frequency relatively while maxillofacial department, otorhinolaryngology department and Internal medicine department accounted for 5.4 percent of the biopsies submitted. While interventional radiology submitted 2.6 percent of biopsies.

Biopsy submitting department	Frequency	Percent
Gynecology and obstetrics	691	38.8
Surgery	688	38.6
Pediatrics	2	0.1
Internal medicine	96	5.4
ENT	97	5.4
Dermatology	17	1.0
Interventional radiology	46	2.6
Ophthalmology	24	1.3
Maxillofacial	96	5.4
Neurosurgery	26	1.5
Total	1783	100.0

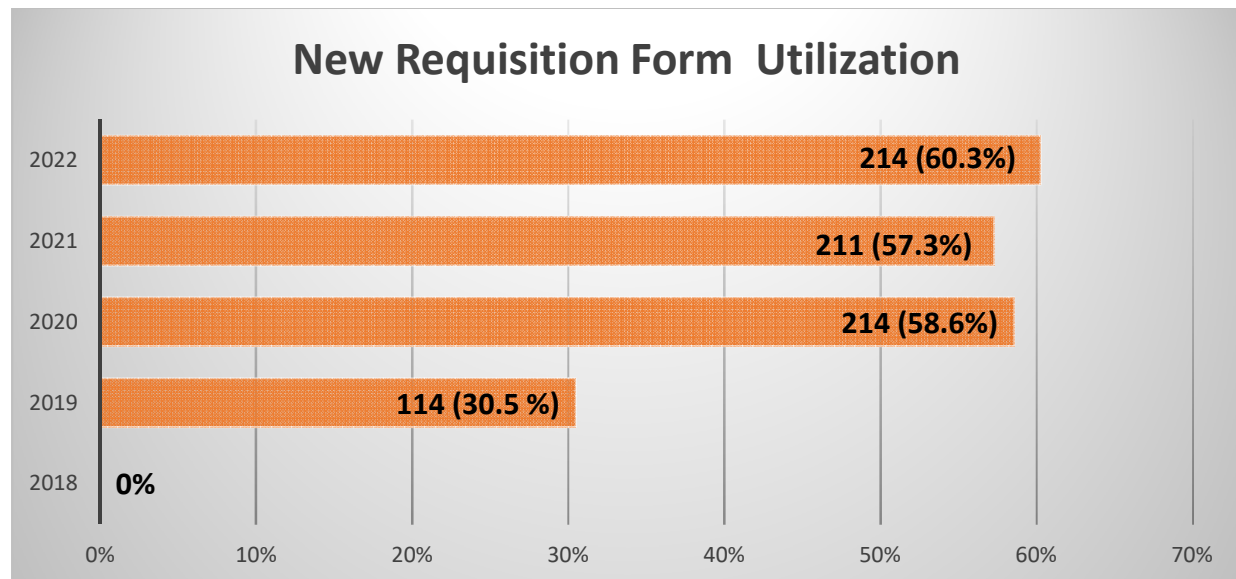
5.1.3 Remuneration for Pathology Lab Services

Among the 1783 biopsies analyzed, 1058 (59.3%) were remunerated through regular payment, 546 (30.6%) through private, and the remaining 179 (10%) had free insurance policy.



5.1.4 Updated Pathology Requisition Form utilization

One of the interventions applied as part of quality improvement program was development of a new updated single requisition form for histopathology, hematopathology and gynecologic and non-gynecologic cytopathology. The overall updated request form utilization was only 42.2%. The utilization of the newly adopted requisition form has been increasing over the past five years, increasing from 0 in 2018 to 114 (30%) in 2019, to 214 (60 %) in 2022.



5.2. Pre-Analytic factors

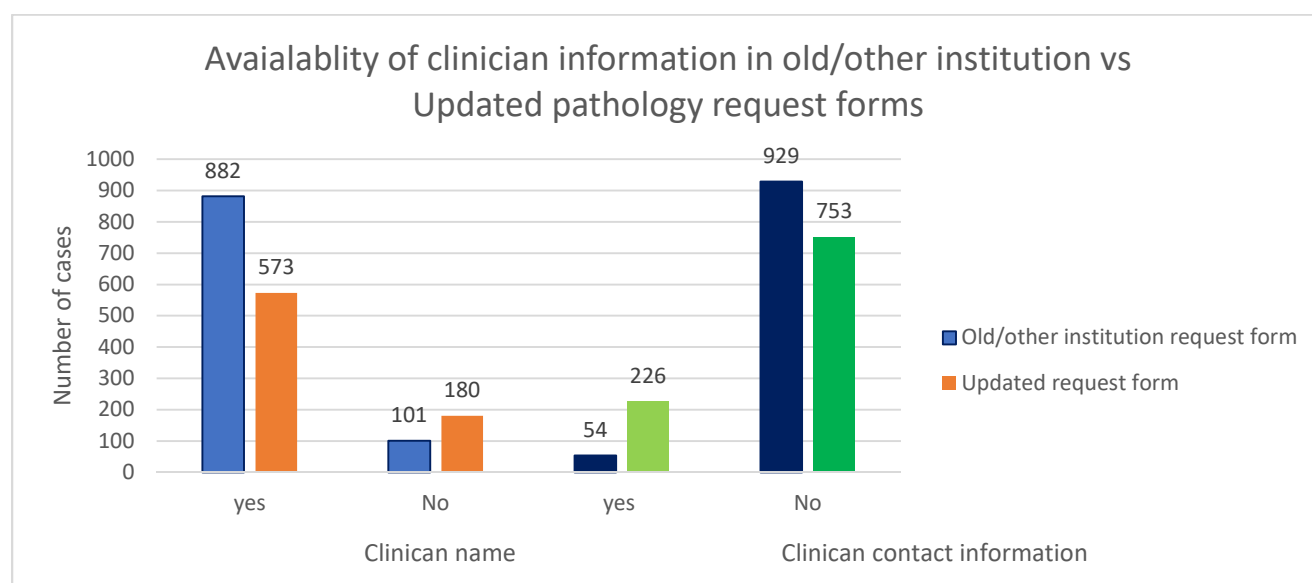
5.2.1 Patient identification

Among the 1783 reviewed (requisition form and electronic data), 100% of forms have patient's full name, sex was available in 98.9%, 1270 (71.2 %) of samples originated from female patients, and 493 (27.7%) from male. The age of patients ranged from 4 months to 80 years with mean of 40.4 years. Age of the patient was not available for 27 of 1783 (1.5%). Patient record number was not provided in 127 of the 1783 cases (7.2 %) and patient contact number was not provided for 72 cases (4 %) of the cases.

5.2.2 Clinician's name and information

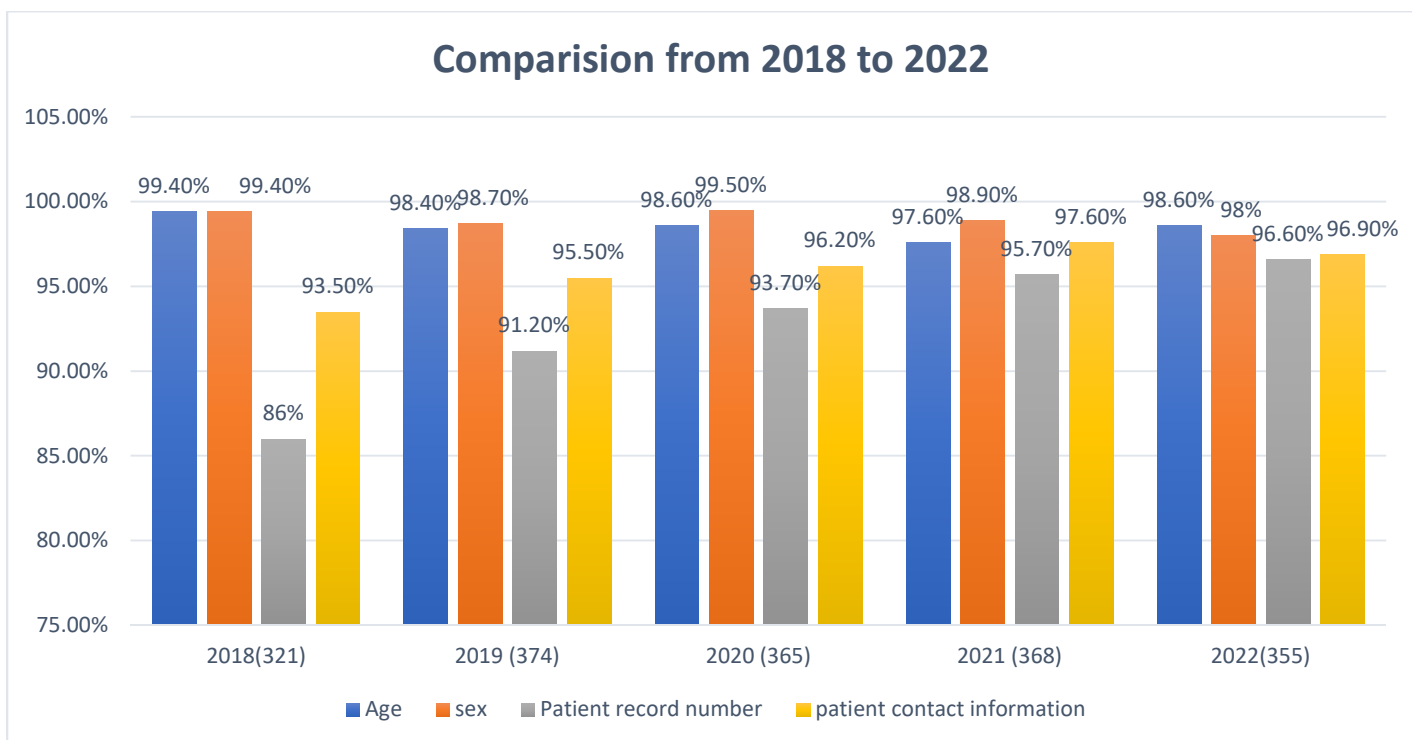
Out of 1783 biopsy cases reviewed, requisition form was available for 1736, and, out of these, managing clinician's name was provided for 1465 (82.2%), but contact number for clinicians was only available for 280 (15.7%) of the cases. Old requisition form and informal and/or requisition forms of other institutions were used in majority of forms reviewed when compared to the SPHMMC's formal requisition form - 882 of 983 (89.7%) vs 573 of 753 (76%). In

comparison to the former, the new requisition form has significantly higher percentage of clinician contact number (58 of 983 (5.5%) vs 226 of 752(30 %)).



The trend over the past five years has been variable for different factors, with some showing improvement while others are on decline. The utilization of the newly adopted formal requisition form increased from 2018 to 2022. Age and sex are written constantly (98.4% to 99.4%) over the five-year period, highest being 99.4% in 2018 for age and 99.5% in 2020 for sex. Recording of patient's medical registration number (MRN) and patient contact number increased steadily from the year 2018 to 2022 - from 86% to 96.6% and from 93.5% to 96.9%, respectively. Percentage of forms having clinician's name declined from 2018 to 2021 with slight increase in 2022, while those containing contact number of clinicians increased with the adoption the new requisition form, though still remaining less than one-quarter of cases.

Table: Summary of pre-analytic factors over the 5-year study period					
Year (Number of cases)					
Variables	2018(321)	2019 (374)	2020 (365)	2021 (368)	2022(355)
Updated request forms utilization	0(0%)	114 (30.5%)	214 (58.6 %)	211 (57.3%)	214 (60.3%)
Age	320(99.4%)	368 (98.4%)	360 (98.6%)	359 (97.6%)	350 (98.6%)
Sex	320(99.4%)	369 (98.7%)	363 (99.5%)	364 (98.9%)	348 (98%)
Patient record number	276 (86%)	341 (91.2%)	342 (93.7%)	352 (95.7%)	343 (96.6%)
patient contact Info	300 (93.5%)	357 (95.5%)	351 (96.2%)	359 (97.6%)	344 (96.9%)
Clinician name	295 (91.9 %)	313 (83.7%)	298 (81.6%)	270 (73.4%)	289 (81.4%)
clinician contact	8(2.2%)	67 (17.9%)	85 (23.3%)	62 (16.8%)	59 (16.6%)



5.2.3 Clinical data

5.2.3.1 Clinical information

Clinical information was not available for 414 of 1783 (23.2%) requisition forms reviewed. Of this 308 (74.6 %) of them were biopsies submitted by different departments from within SPHMMC. St. Luke hospital contributed for 26 (6%) and St. Peter and Ras Desta Hospital contributed for 17 (4.1%) of overall missing clinical information on requisition forms.

	Available	Not Available	Total	Percentage
Saint Paul Hospital	1079	309	1388	22.26%
Zewditu Memorial Hospital	68	23	91	25.27%
Ras Desta Hospital	115	17	132	12.88%
St peter Hospital	26	17	43	39.53%
Black Lion Hospital	14	0	14	0
Chanco Health Center	4	0	5	0
St. Luke Hospital	10	26	36	72.22%
Others	32	14	46	30.43%
Werabe specialized Hospital	6	3	9	33.33%
Yekatit 12 Hospital	8	0	8	0
Wolayita University Hospital	7	4	11	36.36%
	1368	414	1783	23.22%

Among the 414 forms without a clinical history, most were from the Department of Gynecology and Obstetrics 218 (52.7%), followed by Department of Surgery 162 (23.5%). In comparison, all cases from department of Dermatology 17/17 (100%) and most of the cases from Department of Dental and Maxillofacial Surgery 94/96 (97.9%) had adequate clinical information.

Availability of clinical information with submitting department					
	Available	Not Available	Total	% Of missing clinical information per dept.	% of clinical info missing overall
Gyn/obs	473	218	691	31.5%	52.7%
Surgery	526	162	688	23.5%	39.1%
Pediatrics	2	0	2	0.0%	0.0%
Internal medicine	90	6	96	6.3%	1.4%
ENT	89	8	97	8.2%	1.9%
Dermatology	17	0	17	0.0%	0.0%
IR	38	8	46	17.4%	1.9%
Ophthalmology	17	7	24	29.2%	1.7%
Maxillofacial	94	2	96	2.1%	0.5%
Neurosurgery	23	3	26	11.5%	0.7%
Total	1369	414	1783	23.2%	23.2%

5.2.3.2 Clinical diagnosis

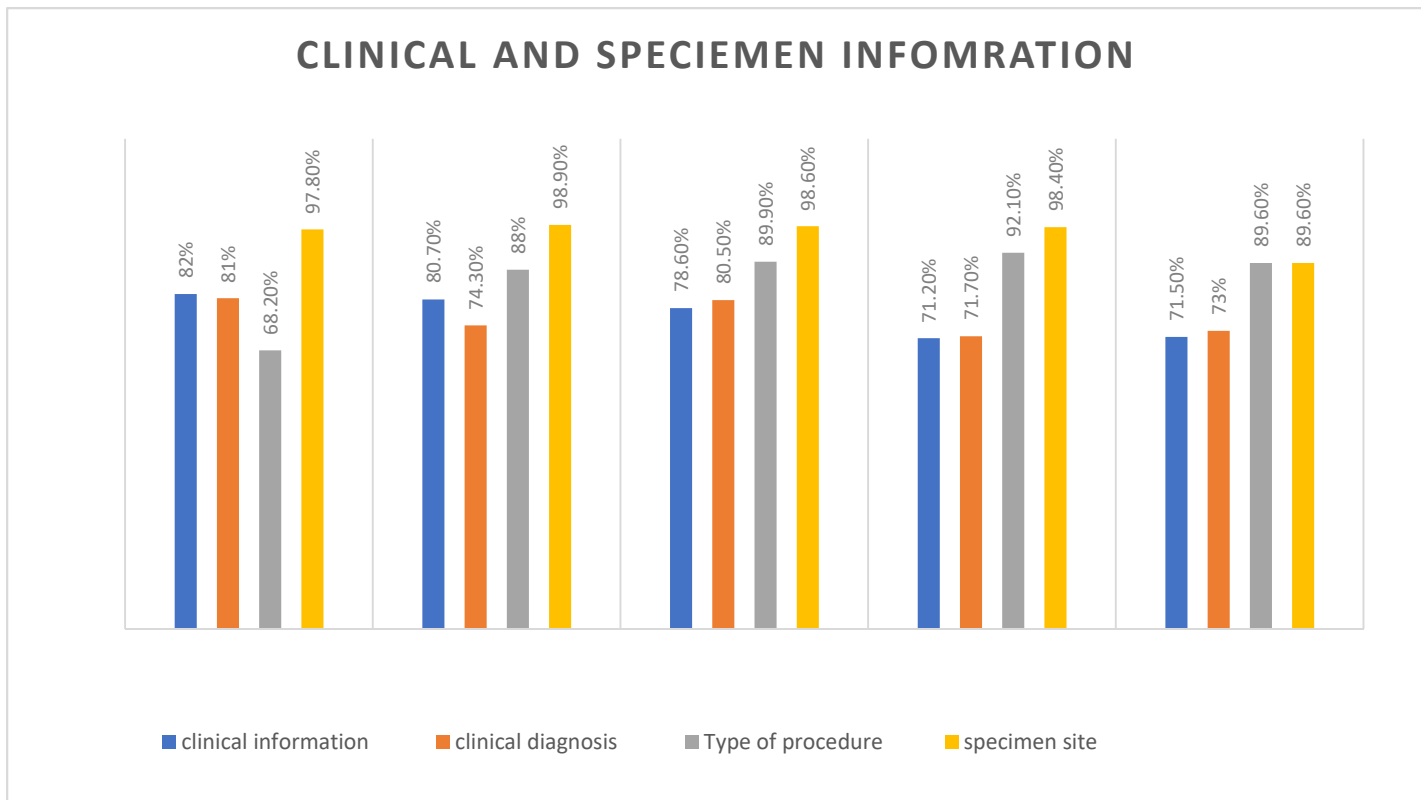
A total of 428 of 1783 (24%) requisition forms lacked working clinical diagnosis. Of this, most were from the Department of Surgery 184 (42.9), followed by the Department of Gynecology and Obstetrics 152 (35.5%) and Department of Otorhinolaryngology 35 (8.2%). In proportion to number of biopsies submitted per department, requisition forms originating from the Department of Otorhinolaryngology lacked clinical diagnosis higher than in other departments 35/97 (36.1%).

5.2.3. Type of procedure, specimen site and date

Specimen site was available for most of the cases (98.5 %) and type of procedure done was available in 86 percent (250 of 1783) of the cases, and date of request is mention in 97% of the requestion forms.

Availability of information on clinical and other details of patient as well as on biopsy were variable: clinical information declined from the year 2018 to 2022 (from 82% to 71%); working clinical diagnosis was available in higher percentage in 2018 (81%) and 2020 (80.5%), with the lowest in 2021 (71.7%); type of procedure done showed steady increment - from 68.2% in 2018 to 92% in 2021, with mild decline in 2022 to 89.6%.

Table: Summary of pre-analytic factors over the 5-year study period					
Variables	Year (Number of cases)				
	2018(321)	2019 (374)	2020 (365)	2021 (368)	2022(355)
clinical information	264 (82%)	302 (80.7%)	287 (78.6%)	262 (71.2%)	254 (71.5 %)
clinical diagnosis	260 (81%)	278 (74.3%)	294 (80.5%)	264 (71.7%)	259 (73 %)
Type of procedure	219 (68.2%)	329 (88%)	328 (89.9%)	339 (92.1%)	318 (89.6%)
specimen site	314 (97.8)	370 (98.9%)	360 (98.6%)	362 (98.4%)	351 (98.6%)
Date of procedure	320 (99.7)	369 (98.7%)	357 (97.8%)	344 (93.5%)	351 (98.9%)



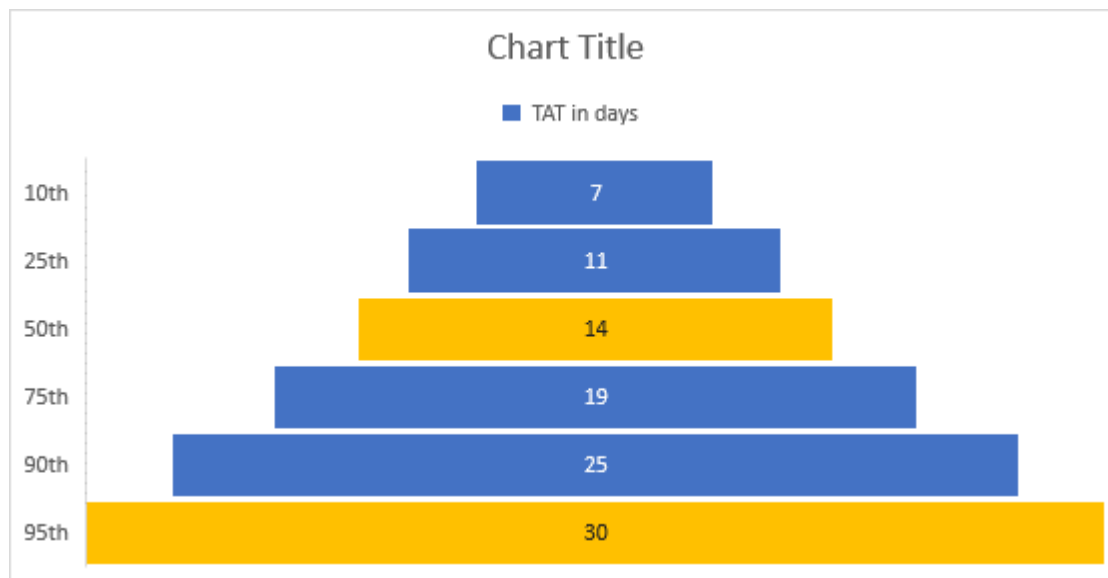
5.3 Analytic factors

All cases had gross, microscopy and diagnosis available in the request forms on sign-out.

5.4. Post Analytic factor

Turnaround time (TAT) refers to the interval between specimen accessioning to report generation. TAT is a clinician satisfier and it is an important indicator of efficiency in the anatomic pathology laboratory (12) The mean TAT of pathology laboratory at St Paul Hospital millennium medical college is 16.29 days and the median was 14 days, ranging from as low as 2 days to as high as 132 days in this study period; 90% were signed out by 26th day; and, of the total, 95% of the biopsies were signed out by 30th day.

There were 38 samples with bone tissue which prolongs TAT due to tissue decalcification. TAT for tissues containing bone ranged between 5 days to 106 days, affecting the overall TAT negatively. Analysis of TAT, done after excluding these 38 cases, failed to show improvement in the mean TAT, which was 16.12 days with 95% of the biopsies still being signed at 30th days.



Looking at the trend of the mean TAT, it showed consistent improvement over the past 5 years, from 18.7 in 2019 to 14.5 in 2022. Overall trends over the past five years shows improvement in the TAT.

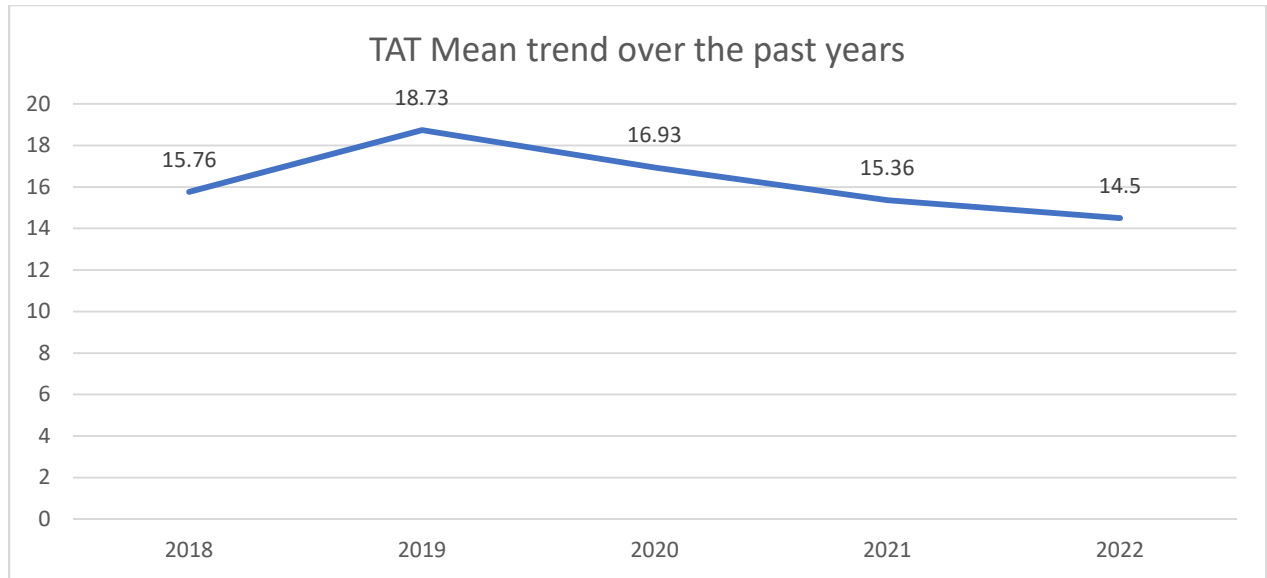


Table: Turnaround time trends over the past five years

TAT in days	2018	2019	2020	2021	2022
Mean	15.76	18.73	16.93	15.36	14.5
Median	14	17	14	13	13
25th percentile	12	14	9	10	9
50th percentile	14	17	14	13	13
75th percentile	17	20	20.5	16	18
95th percentile	27.9	36.5	35.7	28.5	29
100th percentile	78	89	132	127	53
Range	6 to 78	3 to 89	2 to 132	2 to 127	2 to 53

6. Discussion

In our study patients name was available in all of the cases while age and sex of the patients were missing in 1.5 and 1.1 percent of the request forms respectively; This figure was lower in comparison to studies done in Africa and Asia. On published study done in South Africa showed age and sex of the patients were not provided in 3.7 and 4.9 %, respectively. Similarly, studies done in Nigeria and Pakistan showed age was missing in 25 percent and 5.8 percent of the request forms. (8,9,10). Although this is lower figure in comparison to African and far east countries, ideally patient identification should be complete in 100 percent of the cases since it has implication on the overall quality of the pathology report.

Managing clinician's name and contact information was available in 82.2% and 15.7% of the cases, respectively. This figure is higher than seen in studies in Africa, but lower than figures in demonstrated in Asia. In comparison to a study done in Nigeria, clinician name was provided in 92.6% of requisition forms. One study done in Pakistan showed the name of requesting clinician or any contact information was present in only 23%. (8,9).

Possible explanation for SPHMMC's pathology department low performance, particularly regarding clinician's contact information, could be high utilization of earlier pathology request forms and other institution requests forms, since these only had a designated space for managing clinician name but not clinician contact. The utilization of updated pathology request form has been increasing over the past five years and this will possibly improve availability of this information.

In the current study clinical information was not available in 23.4 % (414/1783) and clinical diagnosis was not available in 24% (428/1783) of the cases. This figure is lower in comparison to study done in Africa, Nigeria 50% and Pakistan which showed 34 percent of the cases that didn't have clinical history or diagnosis but much higher in comparison to study done by CAP involving multiple countries in different continent involving United states, United Kingdom, Canada, Belgium, Australia, Hong Kong and New Zealand which showed clinical history to be missing only in 0.62 %, the rate at the 10th percentile was 3.01%, and at the 90th percentile, 0.08%. Similarly, a study done in United Kingdom, Sheffield adequate clinical information was absent in 6.1% of the cases. (5,7,8,9) Similarly clinical history is one of the most crucial aspects of a pathology request form which is currently missing in 1 in four pathology request forms.

Most pathology request forms with incomplete clinical information and clinical diagnosis are from St Paul Millennium medical college (74.6%), Zewditu memorial Hospital (5.5) followed by Ras Desta hospital and St. peters Hospital (each 4.1%). When incomplete clinical analyzed in comparison with the number of biopsies submitted, St. Luke hospital has the highest rate of not providing clinical information. (26/36, 72.2%). Out of the 414 cases without clinical information 91.9 percent is contributed by gynecology and obstetrics and surgical department taking 52.8 and 39.1 percent respectively. Possible reasons for this are pathology request forms being filled out by medical personnel not being involved, lack of awareness of the critical importance and its implications in the final pathology report and further patient management. Lack of clinical history and diagnosis also has been shown in multiple studies that results in prolongation of the turnaround time and accuracy of a pathology report.

Type of procedure, specimen site and date of specimen collection were not available in 14, 1.5 and 3 percent of the pathology request forms in comparison study done in South Africa, Tygerberg Hospital which showed type of Specimen and date of specimen collection were not available for 11 and 3 % of the time respectively, pathology request forms in this study had more information regarding specimen site. (10)

The mean turnaround time for this study was 16.29 days (10th–90th percentile range, 10–26 days). This figure is slightly shorter compared to a study in Ethiopia by Okbazgi G which showed average TAT 18 days with range of 7-30 days and a study done in Africa, Nigeria by Macharia BN et al which showed mean TAT of 22 days. This number is comparable to a study done in East Africa, Kenya which demonstrated the average TAT was 16.2 days from the time of accession to dispatch with a range of 3-59 days. But the TAT in this study was longer than a study done in West Africa, Nigeria teaching hospital by Emmanuel I et al with a mean turnaround time of 7.5 with range of 3 to 18 and another study done teaching hospital in Asia, Pakistan showed the laboratory turnaround time of 5.6 with range of 2 to 15 (16,17,18,19). In another study done by CAP study which including 56 institutions, turnaround time was much shorter 2.72 calendar days (10th–90th percentile range, 1.2–6.3 days). The turnaround time in our study is also longer than the target put by the department which is 14 days and also what is recommended by the Royal Pathology of United Kingdom 80% of diagnostic cases within 7 days and, and 90% reported within 10 calendar days. (13,14,20)

One factor that might be possibly considered for not achieving the bench mark of 14 days would have been inclusion of tissue containing bone which is subjected to decalcification. In this study out of the 1783 cases 38 cases were tissue containing bone. But even after the exclusion of these 38 cases both the mean turnaround time (16.29 vs 16.1) and the 95th percentile (30 vs 30) failed to show improvement.

7. Limitation of the study

8. Conclusion

Among the key pre-analytic factors analyzed in this study, patient identification ... Performance improvement in these quality metrics is crucial since, as demonstrated in multiple studies, they affect the final quality of the pathology report.

All the pathology requisition forms and electronic formats analyzed have complete availability of information on the gross, microscopic and diagnostic areas; but, subjecting each of these categories through acceptable quality analysis is too complex and beyond the scope of this research, as this will require specific organ or system based analysis according to acceptable standards.

The post analytical factor analyzed in this study – TAT, which is one of the major proxy for evaluating the overall efficiency of the pathology lab, is found to be longer than the target set by the department as well as the recommendations of CAP and Royal College of Pathologist.

9. Recommendation

Based on the finding of this research, we recommend the following measures

- Encouraging the utilization of updated St. Paul pathology requisition form both in our institution and other institutions using St. Paul's pathology services.
- Proper archiving of a hardcopy pathology report once being signed out.
- Encourage and educate managing clinicians to complete the requisition forms and its implication for a pathology service particularly in regard to accuracy and timeliness of a report.
- Apply strong rejection criteria particularly when critical information in the requisition forms is not available.
- Integrating pathology service with electronic medical record system.

- Increasing the available space available for history and clinical diagnosis on the requisition form.
- Despite improvement over the years, taking in to account the turnaround time in this study is higher than what our department aspires to achieve, hence we recommend further breakdown of factors that contribute to delayed turnaround time as done by the monthly quality meeting by quality management team and early intervention by involving SPHMMC leadership and Quality management team.

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10. Annexes

10.1. Questionnaire

ST. Paul Hospital Millennium Medical College, Addis Ababa, Ethiopia.

Any officer bearing responsibility of filling this request is kindly called on to accurately answer each and all the questions listed.

Unique surgical pathology identifier number

10.1.1 Pre analytic factors

Are this preanalytical information available? 1. If yes 2. If Not available.		
1: Identification		
1.1 patient full name		
1.2 Sex of the patient		
1.3. Patient age or date of birth		
1.4. Patient medical record number		
1.5. Patient contact number		
2: Managing physician contact information		
2.1. Name of the surgeon or clinician		
2.2. Contact information of managing clinician		
3: Clinical information		
3.1. Clinical information		
3.2. Clinical diagnosis		
4: Specimen information		
4.1. Type of procedure		
4.2. Specimen site		
4.3. Anatomic location		
4.4. Date of specimen collection		
4.5. Specimen type	1. Resection	2. Small specimens

10.1.2. Analytic factors

Are this analytic factors (gross, microscopic and diagnosis available) on the pathology report? 1 if it is available 2. If not available or incomplete on the report		
5.: Gross description		
5.1. Number of specimens		
5.2. Size of the specimen		
5.3. Cut surface description		
6: Microscopic description		
7: Diagnosis		
7.1. Anatomic site		
7.2. Procedure		
7.3. Clear diagnostic terminology		

10.1.3. Post analytic factors

8. TAT of surgical biopsies in days	
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10.1.4 Miscellaneous

Miscellaneous questions	
Institution submitting the biopsy	1.SPHMMC 2. Zewditu Hospital 3. Ras Desta Hospital 4.St peters Hospital 5. Black lion Hospital 6. Chanco Health center 7. St Luke hospital 8. Others 9. worabe specialized hospital 10.yekatit 12 Hospital 11. Wolayita university hospital
Department submitting the biopsy	1.Gyn/obs 2. Surgery 3. Pediatrics 4. Internal medicine 5.ENT 6. Dermatology 7. interventional radiology 8. ophthalmology 9. Dental and Maxillofacial 10.Neurosurgery
Insurance policy	1.Regular 2. Private 3. Free

1- Pathology Request Form

DO NOT WRITE IN THIS SECTION. IT WILL BE FILLED AT THE ACCESSION ROOM OF THE PATHOLOGY LABORATORY

Checked and accessed by/ Date/ Time / Comment on specimen condition ACCESSION NUMBER:

10.3 Slide quality evaluation format

SPHMMC: ANATOMIC PATHOLOGY
DEPARTMENT

Slide & Cassette Quality Form

[illegible]

NB: 1=V. Poor; 2=Poor;
3=Good; 4=V. Good; 5=Excellent

Responsible Histotechnologist: _____

Responsible Resident: _____

<i>Fixation/Processing</i>	<i>Microtomy</i>	<i>Staining/Cover slipping</i>
F1- Poor/incomplete fixation	M1- Knife lines	S1- Nuclear too dark/muddy
F2- Inadequate processing	M2- Chatter	S2- Nuclear stain too light
F3- Cell shrinkage	M3- Cracked/torn section	S3- Uneven staining
F4- Incorrect orientation	M4- Section too thick	S4- Section cloudy
F5- Excessive/inadequate calcification	M5- Extraneous tissue floaters/debris	S5- Cytoplasmic/counterstain too light
	M6- Folds	S6- Cytoplasmic/counterstain too dark
	M7- Incomplete section	S7- Desired structures over stained
		S8- Desired structures under stained
		S9- Nonspecific background/precipitate
		S10- Air bubble
		S11- Excessive mounting media
		S12- Excessive digestion/retrieval

		Slide Received	
Date		Resident Signature	
		Senior Sign Out	
Name		Date	Sign