

PREANALYTICAL LABORATORY PERFORMANCE EVALUATION UTILIZING QUALITY INDICATORS BETWEEN PRIVATE AND GOVERNMENT-OWNED HOSPITALS AFFILIATED WITH UNIVERSITY OF SANTO TOMAS

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ABSTRACT

Recent evidences show that most of the laboratory errors are related to the pre-analytical phase, leading to erroneous results and diagnoses. The study focuses on the use of quality indicators (QIs) based on standards made by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) to identify and minimize errors occurring in the total testing process (TTP). Survey questionnaire was given to a random sample of nineteen respondents, eight from privately-owned and eleven from government-owned hospitals, who were mainly chief medical technologists, medical technologists, and laboratory supervisors from University of Santo Tomas (UST) affiliated hospitals. Pre-analytical QIs including misidentification errors, transcription errors, sample collection errors and sample handling and transportation errors were identified by the IFCC Working Group Laboratory Errors and Patient Safety (WG-LEPS). The data gathered were analyzed using Mann-

Whitney U test, Percentile, Linear Regression, Percentage, and Frequency. Results show high level laboratory performances on both private and government-owned hospitals. There is no significant difference between the laboratory performance of the two stated variables. Moreover, among the four QIs, sample handling and transportation errors contributed most to the difference. Outcomes indicate a satisfactory performance between both variables. However, in order to ensure high-quality pre-analytical step output and efficient laboratory operation, constant vigilance and improvements in pre-analytical QIs are still needed. Expanding the coverage of the study including other phases, additional quality indicators, different approaches in evaluating the performance level of the laboratories, and utilization of parametric tests are recommended.

KEYWORDS: Preanalytical phase, Quality indicators, Laboratory performance, Preanalytical error

INTRODUCTION

Medical laboratory test results serve as an instrument for the diagnosis and decision-making of clinical doctors about their patients. According to studies, an estimated 60-70% of clinical decisions regarding a patient's diagnosis, prescription, hospital admission and discharge are based on laboratory test results (Abdollahi & Saffar, 2014). Hence, mistakes made in every step of the total testing process (TTP) can potentially harm and affect the patients' safety. This then gives importance to the identification and establishment of valuable quality indicators (QIs) which measure the processes, performance, and results in a healthcare setting reflecting the healthcare quality of a facility, and are used mainly to compare, measure, monitor, and improve their healthcare services or outcomes for the patients (Quentin et al., 2019). These indicators are crucial in ensuring that every step in the TTP is correctly performed and the best possible health outcomes are delivered. However, current QIs in the medical laboratory tend to focus on the efficiency of analytical processes, despite recent evidence suggesting that most errors occur outside the analytical phase (Plebani, 2012).

The TTP is traditionally divided into three main phases, specifically the pre-analytical phase, analytical phase, and post-analytical phase, in which the preceding phase directly affects the quality performance of subsequent series of activities.

The focus of this study, the Pre-analytical phase, is the first and starting phase wherein the process of test selection and ordering takes place, as well as the sample handling, identification, transportation and storage, from which when error occurs causes a significant decrease in the total quality of laboratory management, test results, and patient safety. The 70% error that this phase contributes to the overall laboratory performance was mainly due to human error and lack of harmonization within the process (Zemlin, 2017). Monitoring of this phase is critical particularly at this time of pandemic wherein the laboratory services are extremely puffed up especially the staff being forced to work in high throughput settings and under pressure and receive enormous workloads (Sheridan, 2020). Thus, to have an objective evaluation and monitoring of the critical aspects of its performance, the Quality Indicators (QI) are identified and established for quantifying the phase quality (Shahangian & Snyder, 2009).

With the goal of making a harmonized list of QIs, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) standardized the reporting system of Quality Indicators by formulating a model that is derived from internationalized data (Lippi & Guidi, 2007). Furthermore, different programs and studies are continuously focusing on the refining and reshaping the quality of laboratory performance by means of better laboratory management and prevention and control of errors that will lead to assurance of providing accurate results for quality patient care and safety.

The aim of the study includes the monitoring, detection, and assessment of the pre-analytical errors in the laboratory process with the use of appropriate quality indicators, which could provide an avenue to redefine and improve the pre-analytical quality of the total testing process of clinical laboratories of private and government-owned hospitals affiliated to University of Santo Tomas. Along with other related studies, reasons for ensuring the highest quality, accuracy, and precision of laboratory outcomes benefiting and improving healthcare could be provided.

RESULTS AND DISCUSSION

Table 1.1 Preanalytical Laboratory Performance Evaluation of Private Hospitals on Misidentification Error

Misidentification Error	Mean	SD	Verbal Interpretation
Number of misidentified samples	.004829	.0021422	High Level
Number of misidentified requests	.002243	.0007390	High Level
Number of samples with fewer than two identifiers	.005343	.0016582	High Level
Number of unlabeled samples	.001014	.0008071	High Level
<i>Overall</i>	.003343	.0009396	High Level

Results revealed that the *number of misidentified requests* was the highest (Mean = .005343, SD = .0016582). This is supported by a study conducted by Dudani et al. (2018) in which the common causes of errors for data entry in a private laboratory was due to incorrect or mismatched patient details, incorrect referring physician and patient demographic details, and mistaken type of test seen on patient request forms which accounted for 47% of the total preanalytical error. Additionally, according to West et al. (2017), an audit of request forms to identify the percentage which does not have complete information regarding the requester cannot be monitored or alert the laboratory workers immediately because an audit in the laboratory mostly does not provide real-time assessment of error incidence, but a survey of error rates at a particular point. This makes the audit not immediately alert users to the quality issues and true error rates with their misidentified requests. However, from the study conducted by Flegar et al. (2016), the highest error rates expressed in percentage under the

misidentification errors indicator were found for the number of misidentified samples, which was 0.06%, while the number of misidentified requests was 0.05%.

This indicates that the private hospitals are susceptible to errors associated with the number of misidentified requests among the misidentification error indicators for having the highest Mean = .005343 and SD = .0016582. However, it is below .05 or 5%, which indicates that the performance level of Private Hospitals is still generally high.

Table 1.2 Preanalytical Laboratory Performance Evaluation of Private Hospitals on Test transcription Error

Test transcription Error	Mean	SD	Verbal Interpretation
Number of outpatients requests with erroneous data entry (test name)	.006229	.0023690	High Level
Number of outpatients requests with erroneous data entry (missed test)	.001371	.0008616	High Level
Number of outpatients requests with erroneous data entry (added test)	.001471	.0010436	High Level
Number of inpatients requests with erroneous data entry (test name)	.000771	.0005648	High Level
Number of inpatients requests with erroneous data entry (missed test)	.001057	.0008904	High Level
Number of inpatients requests with erroneous data entry (added test)	.001786	.0007244	High Level
<i>Overall</i>	.002114	.0007290	High Level

Among the six indicators of test transcription errors, the *number of outpatients requests with erroneous data entry (test name)* was the highest (Mean = .006229, SD = .0023690). This is supported by a study conducted by Plebani et al. (2017), where an order of priority has been assigned based on the importance of the specific indicator developed by IFCC and the difficulty of data collection with one as the highest priority and four as the lowest. The QIs with priority one is mandatory and to be put into practice first. The number of outpatients requests with erroneous data entry (test name) indicator is one of the quality indicators assigned as priority one due to its difficulty maintaining proper laboratory data collection and being prone to errors.

This indicates that the private hospitals are susceptible to error associated with the number of outpatients requests with erroneous data entry (test name) among the test transcription error indicators for having the highest Mean = .006229 and SD = .0023690.

However, it is below .05 or 5%, which indicates that the performance level of Private Hospitals is still generally high.

Table 1.3 Preanalytical Laboratory Performance Evaluation of Private Hospitals on Sample Collection Error

Sample Collection Error	Mean	SD	Verbal Interpretation
Number of samples of wrong or inappropriate type	.005800	.0036647	High Level
Number of samples collected in the wrong container	.003443	.0008304	High Level
Number of samples with insufficient sample volume	.003643	.0011886	High Level
Number of samples with inappropriate sample-anticoagulant volume ratio	.001800	.0026026	High Level
Number of contaminated samples	.002343	.0008867	High Level
Number of hemolyzed samples	.011629	.0034422	High Level
Number of clotted samples	.009986	.0081881	High Level
<i>Overall</i>	.005500	.0025826	High Level

Likewise, among the seven indicators of sample collection errors, the *number of hemolyzed samples* was the highest (Mean = .011629, SD = .0034422). This is supported by the study conducted by Chawla et al. (2012), where hemolyzed samples are the most common causes of sample rejection, with a result of 7 per 1000 samples. In another study conducted by Rizk et al. (2014), the number of clotted samples were also second to the highest on both before and after laboratory performance improvement with the results of 1,584 hemolyzed samples out of 2,314 total samples rejected in phase I, a phase which included data collection for evaluation of the existing process. In phase II, including data collection for evaluation of the process after improvement, 841 hemolyzed samples out of 1,285 total samples were rejected. However, from the study conducted by Arul et al. (2018), from the overall prevalence of preanalytical errors found in 0.43% of the total number of samples received, the most common preanalytical error was inadequate samples followed by clotted samples, diluted samples, and hemolyzed samples having overall frequencies of preanalytical errors of 0.2%, 0.12%, 0.02%, and 0.03%, respectively.

This indicates that the private hospitals are susceptible to error associated with the number of hemolyzed samples among the sample collection error indicators for having the highest Mean = .011629 and SD = .0034422. However, it is below .05 or 5%, which indicates that the performance level of Private Hospitals is still generally high.

Table 1.4 Preanalytical Laboratory Performance Evaluation of Private Hospitals on Sample Handling and Transportation Errors

Sample Handling and Transportation Errors	Mean	SD	Verbal Interpretation
Number of samples not properly stored before analysis	.002686	.0006440	High Level
Number of samples damaged during transportation	.006000	.0029682	High Level
Number of samples transported at an inappropriate temperature	.002000	.0008775	High Level
Number of samples with excessive transportation time	.001357	.0016328	High Level
<i>Overall</i>	.003014	.0013619	High Level

Furthermore, among the four indicators of sample handling and transportation, the *number of samples damaged during transportation* was the highest (Mean = .006000, SD = .0029685). This is supported by the study conducted by Roque et al. (2015), where it is stated that one of the most common preanalytical errors is due to specimen transportation and delivery. Out of 481 samples collected, four were damaged during transport which can influence the diagnosis. The samples are subjected to deterioration or lesser quality that will compromise the following analytical phase. Factors that may contribute to the damaged samples during transportation include mislabeling the container, wrong fixative, and poor preservation.

This indicates that the private hospitals are susceptible to error associated with the number of samples damaged during transportation among the sample handling and transportation error indicators for having the highest Mean = .006000 and SD = .0029685. However, it is below .05 or 5%, which indicates that the performance level of Private Hospitals is still generally high.

Overall, based on Table 1, the Preanalytical Laboratory Performance Evaluation of Private Hospitals in terms of misidentification errors, test transcription errors, sample collection errors, and sample handling and transportation errors are below .05 or 5%, which indicates that the performance level of Private Hospitals, in general, is high.

Table 2.1 Preanalytical Laboratory Performance Evaluation of Government-owned Hospitals on *Misidentification Error*

Misidentification Error	Mean	SD	Verbal Interpretation
Number of misidentified samples	.003108	.0021026	High Level
Number of misidentified requests	.001858	.0009501	High Level
Number of samples with fewer than two identifiers	.003683	.0023218	High Level
Number of unlabeled samples	.001125	.0009353	High Level
<i>Overall</i>	.002442	.0014387	High Level

Results revealed that among the four indicators of misidentification errors, respondents from Government hospitals' most frequently committed error was indicator no. 3 which is '*Number of samples with fewer than 2 identifiers*' (Mean = .003683, SD = .0016582). As standardized by the Clinical and Laboratory Standards Institute (CLSI), the process of accurate patient identification requires a minimum of two unique patient identifiers that should be used when collecting samples for clinical testing or when providing other treatments and procedures to prevent diagnostic errors and inappropriate patient management. However, in an observational study conducted by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE), phlebotomists failed to identify the patient according to CLSI or local guidelines in up to 16% of cases. Data showed that labeling was not carried out in the presence of the patient in nearly one-third of cases, thus leading to rejection rates as high as 0.3% of all samples due to receipt of unlabeled tubes and misidentification error (Mrazek et al., 2020)

This indicates that the Government-owned hospitals are susceptible to error associated with the Number of samples with fewer than two identifiers among the Misidentification error indicators for having the highest Mean = .003683 and SD = .0023218. However, it is below .05 or 5%, which indicates that the performance level of Government-owned hospitals is still generally high.

Table 2.2 Pre-Analytical Laboratory Performance Evaluation of Government-owned Hospitals on *Test transcription Error*

Test transcription Error	Mean	SD	Verbal Interpretation
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Number of outpatients requests with erroneous data entry (test name)	.004467	.0034974	High Level
Number of outpatients requests with erroneous data entry (missed test)	.001858	.0015198	High Level
Number of outpatients requests with erroneous data entry (added test)	.001850	.0018725	High Level
Number of inpatients requests with erroneous data entry (test name)	.001283	.0011668	High Level
Number of inpatients requests with erroneous data entry (missed test)	.001158	.0016189	High Level
Number of inpatients requests with erroneous data entry (added test)	.001967	.0015785	High Level
<i>Overall</i>	.002100	.0017389	High Level

Among the six indicators of test transcription errors, indicator no. 1, which is 'Number of outpatients requests with erroneous data entry (test name),' was the highest (Mean = .004467, SD = .0034974). This is supported by the study conducted by De Gruyter (2017) wherein he also utilized the same Working Group - Laboratory Errors and Patient Safety (WG-LEPS) standard by the IFCC and found out that amongst the six (6) other indicators, 'Number of outpatients requests with erroneous data entry (test name)' is one of the highest contributors in the test transcription error inside the laboratory being the 2nd highest during the years 2014 and 2015, and the 1st highest during the year 2016.

This indicates that the Government-owned hospitals are susceptible to errors associated with the Number of outpatients requests with erroneous data entry (test name) among the Test transcription error indicators for having the highest Mean = .004467 and SD = .0034974. However, it is below .05 or 5%, which indicates that the performance level of Government-owned hospitals is still generally high.

Table 2.3 Pre-Analytical Laboratory Performance Evaluation of Government-owned Hospitals on Sample Collection Error

Sample Collection Error	Mean	SD	Verbal Interpretation
Number of samples of wrong or inappropriate type	.003058	.0019714	High Level
Number of samples collected in the wrong container	.002667	.0012851	High Level

Number of samples with insufficient sample volume	.003142	.0022232	High Level
Number of samples with inappropriate sample-anticoagulant volume ratio	.001083	.0008122	High Level
Number of contaminated samples	.002408	.0019048	High Level
Number of hemolyzed samples	.008867	.0054965	High Level
Number of clotted samples	.005700	.0041158	High Level
<i>Overall</i>	.003858	.0022869	High Level

Likewise, among the seven indicators of sample collection errors, indicator no. 6, which is 'Number of hemolyzed samples,' was the highest (Mean = .008867, SD = .0054965). This is supported by the experiment conducted by Najat (2017) in Sulaimani City, wherein the researcher recorded fifteen (15) types of pre-analytical errors, with hemolyzed samples being the highest number of percentages (9%). Another study conducted by Dikmen et al. (2015) in a government-owned hospital found out that the most commonly reported types of preanalytical errors in the stat laboratory were hemolyzed samples which were 46.4% in biochemistry. Azman et al. (2019) also added that the most prevalent pre-analytical interference and a major source of error producing unreliable laboratory test results is hemolysis of blood samples.

This indicates that the Government-owned hospitals are susceptible to error associated with the Number of hemolyzed samples among the Sample collection error indicators for having the highest Mean = .008867 and SD = .0054965. However, it is below .05 or 5%, which indicates that the performance level of Government-owned hospitals is still generally high.

Table 2.4 Pre-Analytical Laboratory Performance Evaluation of Government-owned Hospitals on Sample Handling and Transportation Errors

Sample Handling and Transportation Errors	Mean	SD	Verbal Interpretation
Number of samples not properly stored before analysis	.002342	.0013146	High Level
Number of samples damaged during transportation	.003175	.0018111	High Level

Number of samples transported at an inappropriate temperature	.001583	.0010143	High Level
Number of samples with excessive transportation time	.000692	.0005143	High Level
<i>Overall</i>	.001942	.0010553	High Level

Furthermore, among the four indicators of sample handling and transportation, indicator no. 2, which is '*Number of samples damaged during transportation,*' was the highest (Mean = .003175, SD = .0018111). This is supported by a study conducted by Najat (2017) wherein among 5,550 samples from public diagnostic laboratories, 39% accounts for the samples damaged during transportation, making it one of the most common types of errors that showed an alarming trend and required corrective actions on the selective hospitals to minimize this type of error. Conditions associated with the damaged samples include the various temperature fluctuations that the samples frequently underwent before reaching the laboratory for analysis, including the not properly air-conditioned and ambient temperatures, the unspecialized containers that are essential to keep the viability of certain samples during specific transport conditions, and lack of training of the staffs.

This indicates that the Government-owned hospitals are susceptible to error associated with the Number of samples damaged during transportation among the Sample handling and transportation error indicators for having the highest Mean = .003175 and SD = .0018111. However, it is below .05 or 5%, which indicates that the performance level of Government-owned hospitals is still generally high.

Notably, the Pre-Analytical Laboratory Performance Evaluation of Government-owned Hospitals in terms of misidentification errors, test transcription errors, sample collection errors, and sample handling and transportation errors are below .05 or 5%, which indicates that the performance level of Government-owned Hospitals, in general, is high.

Table 3 Comparison on the Level of Performance of Private and Government-owned Hospitals Affiliated with the University of Santo Tomas on *Misidentification Errors*

Misidentification Errors	Private		Government-owned		p-value
	N = 7		N = 12		
	Mean	SD	Mean	SD	

Number of misidentified samples	.004829	.0021422	.003108	.0021026	.100
Number of misidentified requests	.002243	.0007390	.001858	.0009501	.384
Number of samples with fewer than 2 identifiers	.005343	.0016582	.003683	.0023218	.120
Number of unlabeled samples	.001014	.0008071	.001125	.0009353	.592
<i>Overall</i>	.003343	.0009396	.002442	.0014387	.142

Table 3 shows the comparison between the Level of Performance of Private and Government-owned Hospitals Affiliated with the University of Santo Tomas on *Misidentification Errors*.

Results revealed that none of the indicators of *misidentification errors* have significant differences as indicated by their p-values, all greater than .05. Although the overall *misidentification errors* of Private Hospitals (Mean = .003343, SD = .0009396) is higher than Government-owned Hospital (Mean = .002442, SD = .0014387), the p-value is .142. This indicates that there is *no significant difference between the levels of performance of the two hospitals in terms of Misidentification Errors*.

Table 4. Comparison on the Level of Performance of Private and Government-owned Hospitals Affiliated with University of Santo Tomas on *Test transcription Errors*

Test Transcription Errors	Private		Government-owned		p-value
	N = 7		N = 12		
	Mean	SD	Mean	SD	

Number of outpatients requests with erroneous data entry (test name)	.006229	.0023690	.004467	.0034974	.100
Number of outpatients requests with erroneous data entry (missed test)	.001371	.0008616	.001858	.0015198	.773
Number of outpatients requests with erroneous data entry (added test)	.001471	.0010436	.001850	.0018725	.902
Number of inpatients requests with erroneous data entry (test name)	.000771	.0005648	.001283	.0011668	.432
Number of inpatients requests with erroneous data entry (missed test)	.001057	.0008904	.001158	.0016189	.650
Number of inpatients requests with erroneous data entry (added test)	.001786	.0007244	.001967	.0015785	.592
<i>Overall</i>	.002114	.0007290	.002100	.0017389	.536

Table 4 shows the comparison between the Level of Performance of Private and Government-owned Hospitals Affiliated with the University of Santo Tomas on *Test Transcription Errors*.

The results from the Mann-Whitney U Test revealed that none of the indicators under *Test Transcription errors* has significant differences as indicated by their p-values which are all greater than .05 ($p > 0.05$). Although the overall *Test transcription errors* of Private Hospitals (Mean = .002114, SD = .0007290) is higher than Government-owned Hospitals (Mean = .002100, SD = .0017389), the p-value is .536. This indicates that there is *no significant difference between the levels of performance of the two hospitals in terms of Test Transcription Errors*.

Table 5. Comparison on the Level of Performance of Private and Government-owned Hospitals Affiliated with University of Santo Tomas on *Sample Collection Errors*

Sample Collection Errors	Private		Government-owned		p-value
	N = 7		N = 12		
	Mean	SD	Mean	SD	
Number of samples of wrong or inappropriate type	.005800	.0036647	.003058	.0019714	.028
Number of samples collected in wrong container	.003443	.0008304	.002667	.0012851	.340
Number of samples with insufficient sample volume	.003643	.0011886	.003142	.0022232	.227
Number of samples with inappropriate sample-anticoagulant volume ratio	.001800	.0026026	.001083	.0008122	.902
Number of contaminated samples	.002343	.0008867	.002408	.0019048	.711
Number of hemolyzed samples	.011629	.0034422	.008867	.0054965	.142
Number of clotted samples	.009986	.0081881	.005700	.0041158	.083
<i>Overall</i>	.005500	.0025826	.003858	.0022869	.083

Table 5 presents the comparison between the Level of Performance of Private and Government-owned Hospitals Affiliated with the University of Santo Tomas on *Sample Collection Errors*.

It can be noted that the Mean Percentage of Error of indicator no.1, which is the ‘*Number of samples of wrong or inappropriate type*’ of *Sample Collection Errors* for Private Hospitals (Mean = .005800, SD =.0036647), is higher than Government-owned Hospital (Mean = .003058, SD = .0019714) with the p-value of .028. This implies a significant difference in the number of samples of wrong or inappropriate type between the two hospitals, with the Private hospitals having the higher percentages of error. However, the study done by Chawla et al. (2010) was not inclined with this study because the variable that received the highest frequency rating was specimen hemolysis at 1.10% for inpatients and insufficient volume for testing at 1.2% for outpatients. Another study with different findings is the one conducted by Gimenez-Marín et al. (2014), which found out that the highest rates were found for the indicators “haemolysed sample” (8.76%).

Generally, though the overall *Sample Collection Errors* of Private Hospitals (Mean = .005500, SD =.0025826) is higher than Government-owned Hospital (Mean = .003858, SD = .0022869), the p-value is .083. This indicates that there is no significant difference between the levels of performance of the two hospitals in terms of *Sample Collection Errors*. This is supported by Gubaton et al. (2020), wherein they found out that private hospitals had a higher mean in the sample collection. Still, the overall data have no significant difference against government-owned hospitals, having only a p-value of less than 1% ($p < 0.001$). According to Plebani et al. (2011), the lack of standardized procedures for sample collection, including patient preparation, acquisition of specimens, and handling or storage, accounts for up to 93% of the errors encountered in the diagnostic process within the laboratory. However, the study conducted by Abdollahi et al. (2014) is not inclined with this study because they have found out that sample collection errors showed great significance in relation to laboratory performance of the hospitals, garnering a total of 20.89% (4685) of pre-analytical errors for outpatient and 28.19% (21,789) for inpatient.

Table 6. Comparison on the Level of Performance of Private and Government-owned Hospitals Affiliated with the University of Santo Tomas on *Sample Handling and Transportation Errors*

Sample Handling and Transportation Errors	Private		Government-owned		p-value
	N = 7		N = 12		
	Mean	SD	Mean	SD	

Number of samples not properly stored before analysis	.002686	.0006440	.002342	.0013146	.650
Number of samples damaged during transportation	.006000	.0029682	.003175	.0018111	.010
Number of samples transported at inappropriate temperature	.002000	.0008775	.001583	.0010143	.261
Number of samples with excessive transportation time	.001357	.0016328	.000692	.0005143	.711
<i>Overall</i>	.003014	.0013619	.001942	.0010553	.068

Table 6 shows the comparison between the Level of Performance of Private and Government-owned Hospitals Affiliated with the University of Santo Tomas on *Sample Handling and Transportation Errors*.

Notably, the Mean Percentage of Error of indicator “*Number of samples damaged during transportation*” from the factor *Sample Handling and Transportation Errors* for Private Hospitals (Mean = .006000, SD = .0029682) is higher than Government-owned Hospital (Mean = .003175, SD = .0018111) with the p-value of .010. This implies that there is a significant difference in the damaged samples received between Private and Government-owned hospitals.

Overall, for the *Sample Handling and Transportation Errors*, it is demonstrated in the results that the Private Hospitals (Mean = .005500, SD = .0025826) is higher than Government-owned Hospital (Mean = .003858, SD = .0022869), with the p-value is .068, which indicates that there is no significant difference between the level of performance of the two hospitals in terms of *Sample Handling and Transportation Errors*.

Table 7. Overall values of each IFCC WG-LEPS Indicators

	Private	Government-owned	p-value
IFCC Indicator	N = 7	N = 12	

	Mean	SD	Mean	SD	
Misidentification Error	.003343	.0009396	.002442	.0014387	.142
Test transcription Error	.002114	.0007290	.002100	.0017389	.536
Sample Collection Error	.005500	.0025826	.003858	.0022869	.083
Sample Handling and Transportation Errors	.003014	.0013619	.001942	.0010553	.068

Table 7 shows the values for each IFCC WG-LEPS indicator for both Private and Government-owned Hospitals Affiliated with the University of Santo Tomas.

Notably, the indicator for “*Sample Handling and Transportation Errors*” with a p-value of .068 contains the highest p-value among the four pre-analytical phase quality indicators. It is followed by “*Sample Collection Error*” with a p-value of .083, “*Misidentification Error*” with a p-value of .142, and least is the “*Test transcription Error*” with the lowest p-value of .536. This indicates that the “*Sample Handling and Transportation Errors*” is the quality indicator that contributes the most to the difference between the Laboratory Performance of Private and Government-owned Hospitals.

This is supported by a study conducted by Gubaton et al. (2020); the variable “*Sample handling and Transportation*” as one of the common errors in the pre-analytical phase, has shown accuracy, precision, and reliability in the performance of the laboratories and are of great help in assessing and comparing results between the Government-owned and Private hospitals and was classified under Quality indicator Priority “1”. In a study conducted by Najut (2017), it was found out that out of 10 different hospitals included in his study, it was “*Delay in sample transportation*” that contributed the most (35-40% of pre-analytical error), and also a high prevalence of sample not being stored properly / “*sample not on ice*” (15-20%) both of which are factors under *Sample Handling and Transportation Errors*. Felder (2011) added that sample quality could be compromised by exposure to extremes of temperature and physical forces during transportation which mainly contributes to the errors during the pre-analytical phase of laboratory testing. Lastly, a study by Mrazek (2017) done on European laboratories reported proportions of unsuitable samples due to inappropriate time and temperature conditions during sample transportation can be as high as 3.4% and 1.2% of all samples received, respectively and 1.9% in relation to the errors analyzed.

However, the study done by Mrazek, C. (2020) was not inclined with this result because he instead found out that it was the sample collection error (which accounts for about 40% of all errors) is the one with that contributed the most to the errors between the hospitals included in his study which is then followed by Misidentification error (accounts for about 30% of all errors), Test transcription error (accounts for about 20% of all errors), Sample handling and transportation (accounts for about 10% of all errors).

METHODOLOGY

Research Design

A descriptive-comparative research design had been employed in this study. The research had utilized quantitative data collection through the use of a structured questionnaire that had been employed online as a one-time survey only through the use of email (google forms) as the data collection platform for organized data gathering to evaluate the pre-analytical laboratory performance of private and government-owned hospitals affiliated to University of Santo Tomas based on quality indicators provided by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The quantitative survey form had been divided into four categories, corresponding to the possible errors encountered in the preanalytical phase of laboratory testing. This includes the misidentification errors, test transcription, sample collection, and sample handling and transportation errors. Through the use of these indicators, the level of pre-analytical laboratory performance of the private and government-owned hospitals affiliated to University of Santo Tomas had been determined and compared with each other.

Research Locale

The locale for this research is within Metro Manila and in Bulacan, Philippines for the researchers to have ease of access to the different private and government-owned hospitals for data gathering with regards to their laboratory performance with the use of Quality Indicators (QI). There are a total of 20 established hospitals within Metro Manila and 1 from Bulacan, 8 hospitals that are privately-owned and 13 government-owned hospitals affiliated to University of Santo Tomas.

Sampling Procedure

The researchers created a quantitative survey (answered numerically) based on the standards made by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) that was submitted and approved by the Ethics Board Committee of the University of Santo Tomas. After the approval, revisions are made to improve the survey questionnaire and be comprehensive. Consequently, the researchers disseminated the survey through purposive sampling technique with a questionnaire through email (google forms) to the clinical laboratory's section supervisors, chief medical technologist, or medical technologist of the chosen hospitals.

Data Collection

The researchers distributed the questionnaires online through the use of email (google forms) as the data collection platform for organized data gathering. The researchers included

in the form the reason for collecting the data and assure that all information to be gathered are strictly confidential and are solely used for the research study only. A total of 21 survey questionnaires were sent, however only 19 University of Santo Tomas (UST) affiliated hospitals agreed to answer the questionnaire, eight (8) from privately-owned and eleven (11) from government-owned hospitals. The responses gathered are then arranged and tallied.

Data Analysis

The Preanalytical laboratory performance had been evaluated through the tabulation of the gathered and tallied data from the instrument and by using the following statistical tools:

Frequency. This has been used to determine the number of times errors occurred in each quality indicator of the preanalytical testing phase.

Formula:

$$f = n$$

Where: f = frequency

n = number of times the data value occurs per quality indicator

Percentage. This has been used to determine the proportion of the number of errors in each quality indicator of the preanalytical testing phase in relation to the total number of samples received in each private and government-owned hospital.

Formula:

$$\% = \frac{f}{N} \times 100$$

Where: % = percentage

f = frequency

N = total number of sample/request received

Percentile. This statistical tool has been used to compare a particular percentage score of a certain indicator of one hospital to the percentage scores of a certain indicator from the rest of the hospitals.

Formula:

$$P = \left(\frac{n}{N} \right) \times 100$$

Where: P = percentile

n = ordinal rank of a given value

N = number of values in a data set

Verbal Interpretation. Based on the criterion set by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the verbal interpretation had been set as follows:

25th percentile value - High level of performance

50th percentile value - Medium level of performance

75th percentile value - Low level of performance

Mann-Whitney U Test. This has been used to determine the significant difference in the quality indicators between private and government-owned hospitals affiliated with the University of Santo Tomas.

Formula:

$$U_1 = n_1 n_2 + \frac{R_1(R_1+1)}{2} - R_1$$

$$U_2 = n_1 n_2 + \frac{R_2(R_2+1)}{2} - R_2$$

Where: R = sum of ranks in the sample
n = number of items in the sample

CONCLUSION

The Pre-Analytical Laboratory Performance Evaluation of Private Hospitals and Government-owned Hospitals Affiliated to University of Santo Tomas for the 4 indicators (misidentification errors, test transcription errors, sample collection errors, and sample handling and transportation errors) are all of High Level. The study found out that there is no significant difference between the Laboratory Performance of Private and Government-owned Hospitals Affiliated to University of Santo Tomas in terms of the 4 indicators used (misidentification errors, test transcription errors, sample collection errors, and sample handling and transportation errors). Furthermore, among the 4 pre-analytical phase quality indicators (misidentification errors, test transcription errors, sample collection errors, and sample handling and transportation errors), the sample handling and transportation errors has the most significant effect ($p = 0.068$) in the difference between the Laboratory Performance of Private and Government-owned Hospitals Affiliated to University of Santo Tomas.

The accuracy, precision, and quality of pre-analytical laboratory performance of both the private and government-owned hospitals could be measured and evaluated through a set of indicators/parameters. The performance level of both Private and Government-owned hospitals affiliated with the University of Santo Tomas was compared using the same parameters (misidentification errors, test transcription errors, sample collection errors, and sample handling and transportation errors) as a reference. To sum it up, both Private and Government-owned Hospitals affiliated with the University of Santo Tomas demonstrated High-Level Performance, even at this time of the pandemic, backed by the data collected in this study. Pre-analytical errors done by these hospitals were kept at a minimum which shows that quality is still monitored in their respective laboratories. The hospitals have very little differences in preanalytical errors but show no significance, though study limitations can be part of. Therefore, the level of performance shown by these hospitals suggests that the quality of their service and the kind of healthcare they are offering is still of the highest quality. With the researchers' findings, it may be inferred that there is quality in the total testing process of the hospitals affiliated with the University of Santo Tomas. Quality control and quality assurance may be frequently monitored as their performance for the pre-analytical phase are of high level. Additionally, delivering quality patient care starts with the pre-analytical phase, which is the reason why this step is critical and must be thoroughly monitored.

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The researchers did not have a conflict of interest in any form (personal, financial, proprietary, or professional) with the sponsor/grant-giving organization, the study, the co-investigators/personnel, or the site. The researchers certify that they had abided by the ethical principles in this document. The researchers had submitted a final report of the proposed study to the UST Faculty of Pharmacy Research Ethics Office. They did not commence with data collection until they received an ethics review approval from the FOP Research Ethics Committee.

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